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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,055	11/21/2003	John M. Williams	2478.2018-001	9135

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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11/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,055	WILLIAMS, JOHN M.	
	Examiner	Art Unit	
	Shirley V. Gembah	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/14/07</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The response filed **8/15/07** presents remarks and arguments to the office action mailed **4/11/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 9/04/07 is acknowledged and has been reviewed.

Status of Claims

Claims 1-28 are pending.

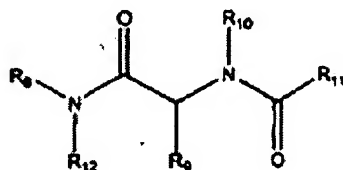
Exhibits

The Exhibits D-F submitted on 3/16/07 is acknowledged and has been reviewed carefully. However, the rejections below are maintained. The claims as read are not distinguishable from graft versus host disease. A graft is a transplanted cell. See enclosed NIH reference. See underlining sections in the enclosed document.

Maintained Claim Rejections - 35 USC § 102

Claim 1-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Sneddon et al. WO 01/87849.

Sneddon discloses current claims 1 and 2, a method of inhibiting tissue transplant, as graft versus host disease, (see page 14, line 30), administering the



compound of formula I

Applicant argues that rejection is not used in the art to refer to GVHD. GVHD is a form of transplant. Bone marrow is a tissue.

The claims recite rejection of a transplanted organ, tissue or cell. The rejection is maintained because GVHD as taught by a cited reference. In GVHD, transplantation is done with bone marrow cell-which is interpreted by the Examiner to be a tissue or a cell and this is well within the claim limitation scope of a transplanted cell. It is the Examiner's view point that the risk of developing GVHD is attributed to a number of factors and that the risk increases with increasing amounts of lymphoid tissue being transferred and the order of risk depends on the organ being transplanted as evidenced by Jamieson et al. (Transplant Int. (1991) 4:67-71) (see pg 70-highlighted) of record. Also, Applicant should bear in mind that the claims are given its' broadest interpretation. Inhibiting rejection of a transplanted organ, tissue or cell would be inherent, regardless of the mechanism. GVHD is a form of transplant. The below is just to support

Examiners stance that GVHD is a form of transplantation, not an introduction of a New Reference.

As to the terms "chronic Rejection" As evidence by The National Institute of health describes Transplantation of bone marrow and solid organs such as kidney, heart, liver and lung remains the treatment of choice for several disease states. Although recent progress has improved the short-term survival of allografts, immunological rejection is still an impediment to long-term survival. Substantial evidence has been accumulated indicating that matching the donor organ and the patient for major histocompatibility complex (MHC) antigens can improve both solid organ and bone marrow graft survival. However little is known about the extent to which minor histocompatibility antigen (MiHA) mis-matches affect graft survival. For example, in patients who have been treated to prevent graft rejection, approximately half of HLA-matched bone marrow recipients develop acute or chronic GVHD and this is believed to result from MiHA mis-matches. Similarly, while short-term solid organ transplant survival is positively affected by MHC matching, long-term graft survival is still poor with only 40% of kidneys surviving more than ten years.

Applicant's argument have been given considerable weight but found unpersuasive.

Maintained Claim Rejections - 35 USC § 103

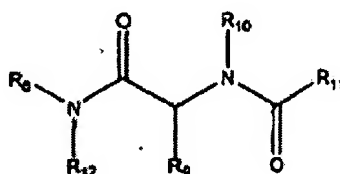
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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneddon et al. WO 01/87849 taken with Sviland et al J. Clin. Pathology 1999, 52:910-913 in view of Jamieson et al. (Transplant Int. (1991) 4:67-71).

Sneddon discloses current claims 1 and 2, a method of inhibiting tissue transplant, as graft versus host disease, (see page 14, line 30), administering the



compound of formula I

Sviland et al. teach GVHD is a complication following bone marrow transplantation (see abstract, wherein (tumor necrosis factor-alpha)TNF- α are important mediators of the cellular damage. (see abstract also).

Jamieson et al. teach that GVHD is a solid organ transplantation effect. The claims recite transplantation of an organ, tissue or cell (see abstract-highlighted sec.). This is well within the claim limitation.

Applicant argues that none of the references cited teach inhibition of transplanted organs in a subject in need thereof.

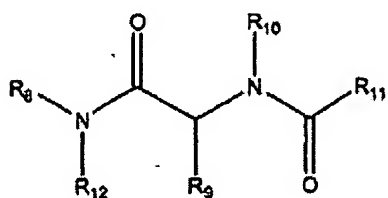
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In response, this is found unpersuasive, the claims are given the broadest claim interpretation. That is a method of inhibiting rejection of a transplanted organ, cell or a tissue. Analyzing the claim interpretation as follows: GVHD the bone marrow rejects the host. The rejection is maintained for the same reason given above.

Maintained Double Patenting

Claims 1-26 remain provisionally rejected under the judicially created doctrine of double patenting over claims 1-20 of copending Application No. 10/719,701 (recently allowed).

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claims are drawn to a composition and method of inhibiting rejection of a transplant organ composition, using formula



in the instant claim with rapamycin or CD40L. The only difference between the instant application and the co-pending application is in the instant claim adjuvant therapy is used while the co-pending claims treat the condition with only the compound of formula I. Thus the claims of the instant application are anticipated by the co-pending application.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembel whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
10/24/07

Ardin H. Marschel 10/28/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER